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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/757,683

01/13/2004

Daniel Perreault

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EXAMINER

STIGELL, THEODORE J

ART UNIT

PAPER NUMBER

3763

MAIL DATE

DELIVERY MODE

11/21/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

Application No.

10/757,683

Applicant(s)

PERREAULT ET AL.

Examiner

Theodore J. Stigell

Art Unit

3763

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 18 December 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-15 and 17-22 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-15 and 17-22 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Drawings***

The drawings filed 12/18/2006 are acknowledged and accepted.

### ***Specification***

The amendments to the specification filed 12/18/2006 are acknowledged and accepted.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 14 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. There is no antecedent basis for "the inner surface".

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4, 6-11, 14-15, and 17-19, and 21-22 are rejected under 35 U.S.C. 102(b) as being anticipated by Sagae (5,176,637). Sagae discloses a catheter comprising an inflatable balloon (3) having a proximal end, a distal end, and an inflation cavity therebetween, a catheter shaft (2) having the inflatable balloon affixed proximate a distal end thereof, the catheter shaft having an inflation lumen (6) fluidly connected to

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the balloon inflation cavity and a guidewire lumen (14) extending through the balloon cavity within a tubular member (1) which is affixed to the inflatable balloon proximate the distal end, and a reinforcing sleeve (14), having a proximal portion and a distal portion with a lumen extending therethrough, wherein the distal portion of the reinforcing sleeve extends into the inflation cavity with at least a portion of the tubular member slidably disposed through the lumen thereof and the proximal portion of the reinforcing sleeve is fixed relative to the catheter shaft and disposed in the catheter shaft inflation lumen, wherein the catheter shaft comprises an outer member (2), wherein the reinforcing sleeve is attached to the outer member at a tack point (see column 5, lines 60-68), and wherein the reinforcing sleeve extends proximally to and past the tack point.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

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Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Sagae (5,176,637). Sagae fails to disclose a reinforcing sleeve that extends at least 15 cm proximally past the tack point. It would have been obvious to one of ordinary skill in the art to modify as claimed as a mere design choice lacking any criticality of length as being merely preferable for strengthening the area depending on the length of area in need of reinforcing where the only difference between the prior art and the claims was a recitation of relative dimensions of the claimed device and a device having the claimed relative dimensions would not perform differently than the prior art device, the claimed device was not patentably distinct from the prior art.

Claims 12-13 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sagae (5,176,637) in view of Kastenhofer (6,659,977). Sagae discloses a catheter comprising an inflatable balloon (3), a catheter shaft (2), an inflation lumen (6), a guidewire lumen (4), a guidewire receiving tube (9), a tubular member (1), an outer member (2) and a reinforcing sleeve (14). (See Figure 1) The reinforcing sleeve is attached to the outer member at a tack point. (See Column 5 Line 60-68) The reinforcing sleeve extends proximally to and past the tack point. Sagae fails to disclose a guidewire tube comprising an inner lubricious layer, a tie layer and an outer layer. Kastenhofer teaches a balloon catheter with a guidewire tube comprising an inner layer (2), outer layer (3) and a mediator layer (4). (See Figure 1) Where the inner layer is taught to have a very low friction coefficient and the outer layer is taught to have a non-kinking capacity. (See Column 5 Line 7-10) Thus, it would have been obvious to one of

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ordinary skill in the art to modify the disclosure of Sagae with the teachings of Kastenhofer to provide a multilayer guidewire tube.

### ***Response to Arguments***

Applicant's arguments filed 12/18/2006 have been fully considered but they are not persuasive. In response to the applicant's argument that Sagae does not disclose a tubular member that is slidably disposed through the reinforcing member, the examiner respectfully disagrees. Sagae discloses that the reinforcing member (14) is preferably made of a coil spring (See column 5, lines 50-55). It appears that if the inner tubular member (1) was pushed in the distal direction the coil spring would stretch and the inner tubular member would slide relative to the coil spring.


### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Theodore J. Stigell whose telephone number is 571-272-8759. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

  
Theodore J. Stigell

  
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